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THE EFFECT OF MODIFICATION ON THE PHYSICAL AND PHYSIOLOGICAL FIT OF POLYCON CONTACT LENSES

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ABSTRACT

This study was undertaken to determine the results of modification on the physical fit and physiological effects of Polycon contact lenses. The differences between the clinical performances of unmodified Polycons and modified Polycons were investigated by employing eleven parameters. Modified Polycons performed superiorly (in a statistically significant fashion) in the areas of movement and centration, patient appearance, wearing time, and patient comfort. No statistically significant difference occurred in the areas of injection, staining, edema, post-refraction, and post-k's.

INTRODUCTION

Corneal edema has been established as a major problem in the wearing of conventional hard (PMMA) contact lenses, for it leads to corneal tissue changes, irregular astigmatism, and a host of lens wear difficulties.[1,2] Brannen reported finding significant corneal edema in over 65% of 700 eyes fitted with PMMA contact lenses. He noted that the fitting method was important in minimizing the magnitude of the edema; however, despite fitting technique variations, the prevalence of edema remained between 48% and 76%.[3]

In 1977, Sarver, Polse, and Harris reported their work with a pilot lens material produced for testing--the Polycon contact lens material. They found that Polycon (silafocon A) contact lenses were helpful in eliminating significant corneal edema. Polycon lenses consist of a mixture of PMMA and silicone. This material offers the double benefit of superior hard lens optical quality and gas permeability. By its permeability characteristics alone, Polycon can supply half the cornea's oxygen needs.[2] If, in addition, the lens is fit similarly to a PMMA lens such that an efficient tear pump mechanism is operational, the cornea's metabolic requirements should be very nearly met. The study of Sarver et al included 46 patients who were unable to wear PMMA lenses because of edema (and associated symptoms). 42 patients were then fitted with Polycons that had the same dimensions as their previously "best-fitting" PMMA lenses. The other four patients were fit with larger diameter lenses in an attempt to reduce contact lens flare. 67% of the patients wore the Polycon

lenses successfully (according to specified criteria); whereas, 28% did not because of discomfort. (These patients commonly reported a dry, scratchy feeling.) Significant corneal edema was not observed in any of the Polycon contact lens wearers. For five patients, the mean corneal thickness change was insignificant after eight hours of wear. Thus, they stated that "the Polycon lens is an important addition to the contact lens armamentarium", and that it was likely that gas-permeable hard lenses would "eventually replace PMMA lenses".[4]

It is worthwhile to note that Sarver, Polse, and Harris could choose from any parameters in fitting their patients with the Polycon pilot material. When, however, the material was marketed in February of 1979, it was available only with restricted parameters. These parameters were based on specifications of a theoretical "ideal lens". Williams, in 1979, described the design development for this "ideal lens". The acceptance of a diameter as being "ideal" was based on evaluating visual and fitting characteristics and patient comfort. The results showed that a 9.5 mm diameter was preferred by 63% of the 105 patients. From that diameter, they determined that the best accompanying optical zone diameter was 8.4 mm. The rationale for the 8.4 mm ozd was that smaller ozd's caused flare and larger ozd's were not as comfortable. Next, edge lift was considered. Here, a study involving 175 patients was carried out over a one-year time period. Utilizing the 9.5 mm/8.4 mm construction, lenses with an edge lift of .12 mm were placed on one eye, while lenses with an edge lift of .06 mm were worn on the other eye. As time progressed, there was a preference for the .12 mm design; therefore, it was considered superior in design. When considering center and edge thick-

ness, it was found that the nature of the silafocon A material allows the lenses to be constructed with center thicknesses as thin as .07 mm (and still maintain the same stability and optical qualities as PMMA). Finally, it was reported that a peripheral edge form simulating a -3.00D lens and of .08 mm edge thickness (requiring lenticular constructions for certain powers) was optimum with respect to lens performance and minimizing sensation.[5]

Thus, the FDA approved the following parameters: overall diameter 9.5 mm, optic zone diameter 8.4 mm, peripheral curve width .5 mm, center thickness .0621 mm, peripheral curve radius 1.5 mm flatter than the given base curve. (Powers and base curves are variable.) In April, 1980, the FDA further approved one smaller diameter lens of 8.5 mm.

It is admittedly of value to find a lens design which serves a large number of patients effectively. It perhaps could be considered as a reasonable starting point in the fitting of Polycon contact lenses. However, should set lens designs based on theoretical ideals be considered as "<u>end</u> points" in the fitting of <u>all</u> patients? Or, must these set lens designs be varied for many patients to reach desirable fitting end points?

It is these questions with which we dealt in the present study. We investigated the effects of modification on the (set-parameter) Polycon contact lenses. We specifically set out to find if (and how) modified lenses would differ from unmodified lenses in some areas which determine a successful contact lens fit: patient comfort, patient appearance, wearing time, fluorescein pattern assessment, conjunctival and perilimbal injection, staining, edema, post-refraction, and post-keratometric findings.

METHODOLOGY

For this study we employed the twenty-two eyes of eleven subjects, all non-contact lens wearers. These subjects were randomly selected from a normal clinic patient population. Patient ages ranged from 19 to 38 years. All patients had refractive errors between plano and -5.00 Diopters, with no more than 1.50 Diopters of refractive astigmatism. In no patient was the corneal toricity greater than 2.50 Diopters. No patients had ocular pathology, nor were any under medication. All subjects had tear break up times exceeding 15 seconds, to negate the influence of low B.U.T.'s in patient comfort.

The twenty-two eyes were randomly divided into three groups. The first group served as a control and received Polycon lenses with design parameters as currently cleared by the FDA. The second group was fit with lenses having a predetermined "standard" lens modification (blending of the bearing zones). The third group was fit with Polycons having "patient-specific" modifications added to the initial modification described for group two.

One experimenter fit all three groups of patients. The first group was fit as dictated by the standard Polycon contact lens fitting guide to obtain the "best fit" possible with the unmodified lenses. ("Best fit" here is defined as the lens which exhibits the optimum clinical appearance--approximate alignment--as assessed by parameters specified by Syntex and including centration of the lens and subjective comfort of the lens.)

The second group of patients was fit with lenses of the

predetermined standard lens modification, consisting of blending the bearing zones. Blending results in an optical zone diameter of 8.2 mm on a 9.5 mm Polycon and 6.8 mm on a 8.5 mm Polycon. The overall diameter was not changed, nor were any other modifications done. These lenses were fit as per the "best fit" possible with this lens design. ("Best fit" in this case is defined as the lens exhibiting the optimum clinical appearance as assessed by the same criteria as used previously.)

The patients in the third group were fit with lenses modified in whatever way necessary to obtain a "custom fit". This is defined as the patient-specific "best fit" assessed according to set criteria. Optimally a thin, even layer of fluorescein should be present throughout the optical zone, bordered by a brighter ring of fluorescein in the periphery, with small channels of dye in a "feathered" appearance between the zones. This is achieved with a base curve/cornea relationship of alignment to slight apical clearance, and a blended periphery. The lens should be comfortable to the patient. Immediately at the end of the blink, the lens should be positioned midway between the center of the cornea and the superior limbus. After the blink, the lens should make a quick movement to the center of the cornea, then reach a stable position at the approximate center of the cornea.

Modifications were made based on an objective assessment of the behavioral performance of the lens, using the "best fit" criteria described. More specifically, lenses showing insufficient tear exchange had their peripheral curve radii flattened by diamond tools, then blended with XPAL and water as needed to achieve proper flow of tears between the optic zone and peripheral region.

Intermediate diameters (8.9 or 9.0) were used when 8.5 mm lenses rested off-center temporally or nasally and near alignment to slight apical clearance could not be achieved with 9.5 mm lenses. Lenses were also re-edged when deemed necessary.

All patients were told to follow the wearing schedule suggested by Syntex for adaptation to Polycon contact lenses. The lenses are maximally worn for four hours on the first day; one hour is added each day thereafter. After adaptation, is was recommended to all patients that lens wear not exceed 12-14 hours per day.

All patients were given the same solutions (and instructions) to care for their lenses. Soaclens (Alcon/BP) was used for soaking; Adapettes was used for wetting; and, Lobob was used for cleaning.[6]

A double-blind experimental design was employed, so that the second experimenter and the patients would not know the group in which they were placed. The second experimenter assessed the clinical performance of all lenses after one week and after one month of lens wear by employing a number of clinical parameters:

1. Wearing Time Achieved. Here the number of hours of wear which were comfortably achieved per day were scaled as follows:

Grade	# Hours
0	>10 hrs
1	9-10 hrs
2	7-8 hrs
3	5-6 hrs
4	3-4 hrs
5	1-2 hrs
6	-0- hrs

2. Subjective Comfort. The patient rated comfort on a scale of 0 to 10 where 0 was no discomfort (i.e. maximum comfort) and 10 was minimum comfort.

3. Patient Appearance. The examiner rated the appearance of the patient on a scale of 0 to 10 where 0 was normal appearance and 10 was distinctively "abnormal" appearance (i.e. head tipped back, excessive blinking, flinching).

4. Movement and Centration. These two clinical parameters were assessed as per the "best fit" criteria (with the aid of fluorescein) and rated accordingly on a scale of 0 to 10 where 0 was excellent and 10 was inadequate.

5, 6. Injection. Both conjunctival and perilimbal injection were considered. The following grading systems were employed:

Conjunctival injection--

Grade		Appearance
0	---	No conjunctival injection
1	---	Very light conjunctival injection; no chemosis
2	---	Light conjunctival injection; no chemosis
3	---	Moderate conjunctival injection; no chemosis
4	---	Moderate conjunctival injection; moderate chemosis
5	---	Severe conjunctival injection; chemosis

Perilimbal injection--

Grade		Appearance
0	---	No perilimbal injection
1	---	Mild conjestion and dilation of limbal vessels
2	---	Moderate conjestion and dilation of the normal limbal vessels
3	---	Severe conjestion and dilation of the normal limbal vessels
4	---	Severe conjestion and dilation of the normal limbal vessels with new vessel budding
5	---	Neovascularization

7. Incidence of Edema. Here any edema was noted and graded as per the following scale:

Grade		Appearance
0	---	No observable edema
1	---	Very light density; no defined borders; no associated stain
2	---	Light density; some definition of borders; no associated stain
3	---	Medium density; borders defined; beginning epithelial breakdown
4	---	Somewhat dense; borders well defined; epithelial breakdown with light staining
5	---	Dense; localized or generalized; edematous corneal lines; epithelial breakdown and staining
6	---	Very dense; generalized; edematous corneal lines; epithelial breakdown with heavy staining; dimple veiling

8. Presence of Staining. This was graded on the following scale:

Grade		Appearance
0	---	No observable stain
1	---	Very light; diffuse; countable
2	---	Light; diffuse; not easily countable
3	---	Moderate; diffuse; not countable; some stipples
4	---	Somewhat dense; some clumping; stippling; some punctate
5	---	Dense; clumping; stippling; punctate; beginning vascular changes
6	---	Very dense; clumping; heavy stippling; punctate; definite vascular changes

9. Post-refraction. Post-refractions were done on all patients and the findings (in diopters) recorded. This information was then ranked according to the following scale:

Grade	Diopters Change (from baseline)
0	0 to .12
1	.25 to .37
2	.50 to .87
3	1.00 to 1.37
4	1.50 to 1.87
5	2.00 to 2.37
6	>2.37

10, 11. Post-keratometer Readings: Vertical and Horizontal. After lens removal, keratometer readings were taken on all patients. This information was ranked according to the following scale:

Grade	Diopters Change (from baseline)
0	0 to .12
1	.25 to .37
2	.50 to .87
3	1.00 to 1.37
4	1.50 to 1.87
5	2.00 to 2.37
6	>2.37

LENS SELECTION INFORMATION

Patient B.H. Refraction: OD -3.50-.75X040 20/15
OS -2.75-.75X135 20/15

Keratometer: OD 42.12/43.00 @90
OS 42.25/43.12 @90

Lenses selected: OD 8.5 dia 7.90 BC -3.75D
OS 8.5 dia 7.90 BC -3.25D

Modification: OD none (control)
OS none (control)

Patient C.H. Refraction: OD -1.25-1.50X180 20/15
OS pl-1.00X020 20/15

Keratometer: OD 42.50/44.75 @90
OS 42.75/44.25 @100

Lenses selected: OD 8.5 dia 7.80 BC -2.00D
OS 8.5 dia 7.75 BC -0.75D

Modification: OD standard blend
OS standard blend

Patient G.R. Refraction: OD -4.75 20/15
OS -4.25 20/15

Keratometer: OD 41.50/42.25 @90
OS 41.00/41.75 @90

Lenses selected: OD 8.5 dia 7.90 BC -4.75D
OS 8.5 dia 8.00 BC -4.25D

Modification: OD custom:

-Applied secondary curve of 8.90 mm and tertiary curve of 9.90 mm using diamond-coated brass radius tools

-Blended periphery with a polish (XPAL)/water series

-Added peripheral curve with velveteen on brass tool (16.00 mm/0.1 mm)

OS custom:

-Applied secondary curve of 9.00 mm and tertiary curve of 10.00 mm using diamond-coated brass radius tools

-Blended periphery with the XPAL/water series

-Added peripheral curve with velveteen on brass tool (16.00 mm/0.1 mm)

Patient B.K. Refraction: OD -3.00 20/15
OS -3.00 20/15

Keratometer: OD 42.87/43.25 @90
OS 43.62/43.50 @90

Lenses selected: OD 8.5 dia 7.80 BC -2.75D
OS 8.5 dia 7.65 BC -3.00D

Modification: OD none (control)
OS none (control)

Patient R.R. Refraction: OD -3.62 20/15
OS -3.62 20/15

Keratometer: OD 44.50/45.75 @90
OS 44.00/45.25 @90

Lenses selected: OD 8.5 dia 7.50 BC -3.75D
OS 8.5 dia 7.55 BC -3.50D

Modification: OD standard blend
OS standard blend

Patient R.G. Refraction: OD -3.75 20/20
OS -3.75 20/20

Keratometer: OD 40.37/41.25 @90
OS 41.00/42.00 @90

Lenses selected: OD 9.5 dia 8.20 BC -3.75D
OS 9.5 dia 8.15 BC -3.50D

Modification: OD custom:

-Overall diameter reduced to 8.9 mm on a 60° cone

-Secondary curve of 9.80 mm/0.35 mm and peripheral curve of 12.00 mm/0.20 mm applied

-New edge applied with velveteen pad and polish

-Periphery blended by polish/water series

OS custom:

-Overall diameter reduced to 8.9 mm on a 60° cone

-Secondary curve of 9.60 mm/0.35 mm and peripheral curve of 12.00 mm/0.20 mm applied

-New edge applied with velveteen pad and polish

-Periphery blended by polish/water series

Patient S.B. Refraction: OD -2.00 20/15
OS -2.00 20/15

Keratometer: OD 44.87/44.87 @90
OS 45.00/44.75 @90

Lenses selected: OD 8.5 dia 7.45 BC -2.00D
OS 8.5 dia 7.50 BC -2.00D

Modification: OD none (control)
OS none (control)

Patient M.B. Refraction: OD -5.00-.50X130 20/15
OS -5.00-.75X005 20/15

Keratometer: OD 43.87/44.25 @90
OS 44.25/45.00 @90

Lenses selected: OD 8.5 dia 7.65 BC -5.25D
OS 8.5 dia 7.55 BC -5.25D

Modification: OD standard blend
OS standard blend

Patient P.B. Refraction: OD -5.00-.25X135 20/15
OS -5.00-.25X075 20/15

Keratometer: OD 46.62/46.37 @90
OS 46.87/47.00 @90

Lenses selected: OD 8.5 dia 7.05 BC -5.25D
OS 8.5 dia 7.15 BC -5.50D

Modification: OD custom:

-Applied secondary curve of 8.00 mm/0.30 mm and tertiary curve of 9.00 mm/0.35 mm

-Blended periphery with the XPAL/water series

-Added peripheral curve with velveteen on brass tool (16.00 mm/0.10 mm)

OS custom:

-Applied secondary curve of 8.20 mm/0.30 mm and tertiary curve of 9.20 mm/0.35 mm

-Blended periphery with a polish/water series

-Added peripheral curve with velveteen on brass tool (16.00 mm/0.10 mm)

Patient K.C. Refraction: OD -1.75 20/15
OS -1.25 20/15

Keratometer: OD 42.37/43.00 @90
OS 42.37/42.87 @90

Lenses selected: OD 8.5 dia 7.85 BC -1.75D
OS 8.5 dia 7.85 BC -1.25D

Modification: OD standard blend
OS none (control)

Patient L.S. Refraction: OD -2.62-1.50X180 20/20
OS -1.87-1.50X180 20/20

Keratometer: OD 41.00/43.50 @90
41.50/43.50 @90

Lenses selected: OD 9.5 dia 8.05 BC -3.25D
OS 9.5 dia 8.00 BC -2.50D

Modification: OD custom:

-Overall diameter reduced to 9.0 mm on a 60° cone

-Secondary curve of 9.60 mm/0.35 mm and peripheral curve of 11.00 mm/0.20 mm applied

-New edge applied with velveteen pad and polish

-Periphery blended by polish/water series

OS none (control)

DATA TABLES

Wearing Time

	Patient	Eye	Group	Prefit Data	1 week visit (Grade)	1 month visit (Grade)
1	BH	OD	control	-------	8 hrs (2)	10 hrs (1)
	BH	OS	control	-------	8 hrs (2)	10 hrs (1)
4	BK	OD	control	-------	5 hrs (3)	9-10 hrs (1)
4	BK	OS	control	--------	5 hrs (3)	9-10 hrs (1)
5	SB	OD	control	-------	8 hrs (2)	9-10 hrs (1)
6	SB	OS	control	-------	8 hrs (2)	9-10 hrs (1)
7	KC	OS	control	-------	9 hrs (1)	12 hrs (0)
8	LS	OS	control	-------	9 hrs (1)	10 hrs (1)
9	CH	OD	standard	-------	11 hrs (0)	12 hrs (0)
10	CH	OS	standard	-------	11 hrs (0)	12 hrs (0)
11	RR	OD	standard	-------	12 hrs (0)	14 hrs (0)
12	RR	OS	standard	-------	12 hrs (0)	14 hrs (0)
13	MB	OD	standard	-------	10 hrs (1)	10 hrs (1)
14	MB	OS	standard	-------	10 hrs (1)	10 hrs (1)
15	KC	OD	standard	-------	9 hrs (1)	12 hrs (0)
16	GR	OD	custom	-------	10 hrs (1)	12 hrs (0)
17	GR	OS	custom	-------	10 hrs (1)	12 hrs (0)
18	RG	OD	custom	-------	12 hrs (0)	12 hrs (0)
19	RG	OS	custom	-------	12 hrs (0)	12 hrs (0)
20	PB	OD	custom	-------	10 hrs (1)	12 hrs (0)
21	PB	OS	custom	-------	10 hrs (1)	12 hrs (0)
22	LS	OD	custom	-------	9 hrs (1)	10 hrs (1)

Comfort

	Patient		Group	Prefit Data	1 week visit	1 month visit
1	BH	OD	control	-------	1½	3
2	BH	OS	control	-------	1½	3
3	BK	OD	control	-------	5	5
4	BK	OS	control	-------	5	5
5	SB	OD	control	-------	3	3
6	SB	OS	control	-------	3	3
7	KC	OS	control	-------	4	3
8	LS	OS	control	-------	1	2
9	CH	OD	standard	-------	1	1½
10	CH	OS	standard	-------	1½	1½
11	RR	OD	standard	-------	1	1
12	RR	OS	standard	-------	1	1
13	MB	OD	standard	-------	2	2
14	MB	OS	standard	-------	2	2
15	KC	OD	standard	-------	2	1
16	GR	OD	custom	-------	1	1
17	GR	OS	custom	-------	1	1
18	RG	OD	custom	-------	1½	½
19	RG	OS	custom	-------	1½	½
20	PB	OD	custom	-------	0	0
21	PB	OS	custom	-------	1	0
22	LS	OD	custom	-------	0	1

Patient Appearance

	Patient	Eye	Group	Prefit Data	1 week visit	1 month visit
1	BH	OD	control	-------	3	3
2	BH	OS	control	-------	3	3
3	BK	OD	control	-------	3½	4
4	BK	OS	control	-------	3½	4
5	SB	OD	control	-------	2	2
6	SB	OS	control	-------	2	2
7	KC	OS	control	-------	3	2
8	LS	OS	control	-------	0	0
9	CH	OD	standard	-------	1	1
10	CH	OS	standard	-------	1	1
11	RR	OD	standard	-------	1	1
12	RR	OS	standard	-------	1	1
13	MB	OD	standard	-------	2	2
14	MB	OS	standard	-------	2	2
15	KC	OD	standard	-------	3	2
16	GR	OD	custom	-------	1	1
17	GR	OD	custom	-------	1	1
18	RG	OD	custom	-------	1½	1½
19	RG	OS	custom	-------	1½	1½
20	PB	OD	custom	-------	0	0
21	PB	OS	custom	-------	0	0
22	LS	OD	custom	-------	0	0

Movement and Centration

	Patient	Eye	Group	Prefit Data	1 week visit	1 month visit
1	BH	OD	control	-------	4	4
2	BH	OS	control	-------	3½	3
3	BK	OD	control	-------	3	2½
4	BK	OS	control	-------	3	3
5	SB	OD	control	-------	2½	2
6	SB	OS	control	-------	3½	3
7	KC	OS	control	-------	3	3
8	LS	OS	control	-------	2	2½
9	CH	OD	standard	-------	1½	2
10	CH	OS	standard	-------	1	1½
11	RR	OD	standard	-------	1½	1
12	RR	OS	standard	-------	1½	2
13	MB	OD	standard	-------	2½	2
14	MB	OS	standard	-------	2½	2
15	KC	OD	standard	-------	1	1
16	GR	OD	custom	-------	1	1
17	GR	OS	custom	-------	1	1
18	RG	OD	custom	-------	1	1
19	RG	OS	custom	-------	1½	1
20	PB	OD	custom	-------	0	½
21	PB	OS	custom	-------	½	½
22	LS	OD	custom	-------	1	1½

Conjunctival Injection

	Patient	Eye	Group	Prefit Data	1 week visit	(Net Grade)	1 month visit	(Net Grade)
1	BH	OD	control	1	2	(1)	2	(1)
4	BH	OS	control	1	2	(1)	2	(1)
3	BK	OD	control	1	2	(1)	2	(1)
4	BK	OS	control	1	2	(1)	2	(1)
5	SB	OD	control	0	0	(0)	0	(0)
6	SB	OS	control	0	0	(0)	0	(0)
	KC	OS	control	0	0	(0)	0	(0)
8	LS	OS	control	0	0	(0)	1	(1)
9	CH	OD	standard	0	1	(1)	1	(1)
10	CH	OS	standard	0	1	(1)	1	(1)
11	RR	OD	standard	0	0	(0)	0	(0)
12	RR	OS	standard	0	0	(0)	0	(0)
13	MB	OD	standard	0	0	(0)	0	(0)
14	MB	OS	standard	0	0	(0)	0	(0)
15	KC	OD	standard	0	0	(0)	0	(0)
16	GR	OD	custom	0	0	(0)	0	(0)
17	GR	OS	custom	0	0	(0)	0	(0)
1	RG	OD	custom	0	0	(0)	0	(0)
19	RG	OS	custom	0	0	(0)	0	(0)
20	PB	OD	custom	0	0	(0)	0	(0)
21	PB	OS	custom	0	0	(0)	0	(0)
22	LS	OD	custom	0	0	(0)	1	(1)

Perilimbal Injection

	Patient	Eye	Group	Prefit Data	1 week visit	(Net Grade)	1 month visit	(Net Grade)
1	BH	OD	control	0	0	(0)	0	(0)
2	BH	OS	control	0	0	(0)	0	(0)
3	BK	OD	control	0	1	(1)	1	(1)
4	BK	OS	control	0	1	(1)	1	(1)
5	SB	OD	control	0	0	(0)	0	(0)
6	SR	OS	control	0	0	(0)	0	(0)
7	KC	OS	control	0	0	(0)	0	(0)
8	LS	OS	control	0	0	(0)	0	(0)
9	CH	OD	standard	0	0	(0)	0	(0)
10	CH	OS	standard	0	0	(0)	0	(0)
11	RR	OD	standard	0	0	(0)	0	(0)
12	RR	OS	standard	0	0	(0)	0	(0)
13	MB	OD	standard	0	0	(0)	0	(0)
14	MB	OS	standard	0	0	(0)	0	(0)
15	KC	OD	standard	0	0	(0)	0	(0)
16	GR	OD	custom	0	0	(0)	0	(0)
17	GR	OS	custom	0	0	(0)	0	(0)
18	RG	OD	custom	0	0	(0)	1	(1)
19	RG	OS	custom	0	0	(0)	1	(1)
20	PB	OD	custom	0	0	(0)	0	(0)
21	PB	OS	custom	0	0	(0)	0	(0)
22	LS	OD	custom	0	0	(0)	0	(0)

Edema

	Patient	Eye	Group	Prefit Data	1 week visit	1 month visit
1	BH	OD	control	0	1	1
2	BH	OS	control	0	1	1
3	BK	OD	control	0	0	0
4	BK	OS	control	0	0	1
5	SB	OD	control	0	0	0
6	SB	OS	control	0	0	0
7	KC	OS	control	0	0	0
8	LS	OS	control	0	0	0
9	CH	OD	standard	0	0	0
10	CH	OS	standard	0	1	0
11	RR	OD	standard	0	0	0
12	RR	OS	standard	0	0	0
13	MB	OD	standard	0	0	1
14	MB	OS	standard	0	0	0
15	KC	OD	standard	0	0	0
16	GR	OD	custom	0	0	0
17	GR	OS	custom	0	0	0
18	RG	OD	custom	0	0	0
19	RG	OS	custom	0	0	0
20	PB	OD	custom	0	0	0
21	PB	OS	custom	0	0	0
22	LS	OD	custom	0	0	0

Staining

	Patient	Eye	Group	Prefit Data	1 week visit	1 month visit
1	BH	OD	control	0	0	1
2	BH	OS	control	0	1	1
3	BK	OD	control	0	0	0
4	BK	OS	control	0	0	1
5	SB	OD	control	0	0	0
6	SB	OS	control	0	0	0
7	KC	OS	control	0	0	0
8	LS	OS	control	0	0	0
9	CH	OD	standard	0	0	0 -
10	CH	OS	standard	0	0	0
11	RR	OD	standard	0	0	0
12	RR	OS	standard	0	0	0
13	MB	OD	standard	0	0	1
14	MB	OS	standard	0	0	0
15	KC	OD	standard	0	0	0
16	GR	OD	custom	0	0	0
17	GR	OS	custom	0	1	1
18	RG	OD	custom	0	0	0
19	RG	OS	custom	0	0	0
20	PB	OD	custom	0	0	0
21	PB	OS	custom	0	0	0
22	LS	OD	custom	0	0	0

Post-Refraction

	Patient	Eye	Group	Prefit Data	1 week visit (Grade)	1 month visit (Grade)
1	BH	OD	control	-3.50-0.75X040	-3.50-0.75X040 (0)	-3.50-0.75X040 (0)
2	BH	OS	control	-2.75-0.75X135	-3.00-0.75X135 (1)	-3.00-0.75X135 (1)
3	BK	OD	control	-3.00 sph	-3.00 sph (0)	-3.00 sph (0)
4	BK	OS	control	-3.00 sph	-3.00 sph (0)	-3.00 sph (0)
5	SB	OD	control	-2.00 sph	-2.00 sph (0)	-2.00 sph (0)
6	SB	OS	control	-2.00 sph	-2.00 sph (0)	-2.00 sph (0)
7	KC	OS	control	-1.25 sph	-1.25 sph (0)	-1.50 sph (1)
8	LS	OS	control	-1.87-1.50X180	-1.75-1.50X175 (.5)	-1.75-1.50X180 (.5)
9	CH	OD	standard	-1.25-1.50X180	-1.25-1.50X180 (0)	-1.25-1.50X180 (0)
10	CH	OS	standard	pl-1.00X020	-0.25-1.00X020 (1)	-0.25-1.00X015 (1)
11	KR	OD	standard	-3.62 sph	-3.75 sph (.5)	-3.50 sph (.5)
12	RR	OS	standard	-3.62 sph	-3.50 sph (.5)	-3.50 sph (.5)
13	MB	OD	standard	-5.00-0.50X130	-5.00-0.50X133 (0)	-5.00-0.50X135 (0)
14	MB	OS	standard	-5.00-0.75X005	-5.00-0.75X008 (0)	-5.00-0.75X003 (0)
15	KC	OD	standard	-1.75 sph	-1.75 sph (0)	-1.50 sph (1)
16	GR	OD	custom	-4.75 sph	-4.75 sph (0)	-4.75 sph (0)
17	GR	OS	custom	-4.25 sph	-4.25 sph (0)	-4.50 sph (1)
18	RG	OD	custom	-3.75 sph	-3.75 sph (0)	-3.75 sph (0)
19	RG	OS	custom	-3.75 sph	-3.75 sph (0)	-3.75 sph (0)
20	PB	OD	custom	-5.00-0.25X135	-5.00-0.25X135 (0)	-5.00-0.25X138 (0)
21	PB	OS	custom	-5.00-0.25X075	-5.00-0.25X078 (0)	-5.00-0.25X075 (0)
22	LS	OD	custom	-2.62-1.50X180	-2.50-1.50X165 (.5)	-2.50-1.50X168 (.5)

Note: The visual acuities which accompanied the above post-refractions were, for all individuals, equal to the pre-fitting visual acuities.

Vertical Post-K's

	Patient	Eye	Group	Prefit Data	1 week visit	(Grade)	1 month visit	(Grade)
1	BH	OD	control	43.00	42.87	(0)	43.12	(0)
2	BH	OS	control	43.12	42.75	(1)	43.25	(0)
3	BK	OD	control	43.25	43.50	(1)	43.50	(1)
4	BK	OS	control	43.50	43.50	(0)	43.75	(1)
5	SB	OD	control	44.87	45.00	(0)	45.00	(0)
6	SB	OS	control	44.75	45.12	(1)	44.62	(0)
7	KC	OS	control	42.87	42.75	(0)	43.00	(0)
8	LS	OS	control	43.50	43.50	(0)	43.25	(1)
9	CH	OD	standard	44.75	44.50	(1)	44.50	(1)
10	CH	OS	standard	44.25	44.37	(0)	44.12	(0)
11	RR	OD	standard	45.75	45.50	(1)	45.75	(0)
12	RR	OS	standard	45.50	45.62	(0)	45.50	(0)
13	MB	OD	standard	44.25	44.37	(0)	44.50	(1)
14	MB	OS	standard	45.00	44.87	(0)	45.00	(0)
15	KC	OD	standard	43.00	42.75	(1)	43.00	(0)
16	GR	OD	custom	42.25	42.37	(0)	42.50	(1)
17	GR	OS	custom	41.75	41.75	(0)	41.75	(0)
18	RG	OD	custom	41.25	41.25	(0)	41.12	(0)
19	RG	OS	custom	42.00	41.87	(0)	41.75	(1)
20	PB	OD	custom	46.37	46.25	(0)	46.37	(0)
21	PB	OS	custom	47.00	47.25	(1)	47.12	(0)
22	LS	OD	custom	43.50	43.50	(0)	43.25	(1)

Horizontal Post-K's

	Patient	Eye	Group	Prefit Data	1 week visit	(Grade)	1 month visit	(Grade)
1	BH	OD	control	42.12	42.00	(0)	42.25	(0)
2	BH	OS	control	42.25	42.00	(1)	42.50	(1)
3	BK	OD	control	42.87	43.12	(1)	43.25	(1)
4	BK	OS	control	43.62	43.50	(0)	43.50	(0)
5	SB	OD	control	44.87	44.75	(0)	44.87	(0)
6	SB	OS	control	45.00	44.75	(1)	44.87	(0)
7	KC	OS	control	42.37	42.37	(0)	42.37	(0)
8	LS	OS	control	41.50	41.50	(0)	41.50	(0)
9	CH	OD	standard	42.50	42.37	(0)	42.50	(0)
10	CH	OS	standard	42.75	42.87	(0)	42.75	(0)
11	RR	OD	standard	43.25	43.50	(1)	43.50	(1)
12	RR	OS	standard	43.50	43.62	(0)	43.50	(0)
13	MB	OD	standard	43.87	43.87	(0)	44.00	(0)
14	MB	OS	standard	44.25	44.50	(1)	44.37	(0)
15	KC	OD	standard	42.37	42.50	(0)	42.50	(0)
16	GR	OD	custom	41.50	41.62	(0)	41.62	(0)
17	GR	OS	custom	41.00	41.12	(0)	41.00	(0)
18	RG	OD	custom	40.37	40.25	(0)	40.25	(0)
19	RG	OS	custom	41.00	40.75	(1)	40.75	(1)
20	PB	OD	custom	46.62	46.62	(0)	46.50	(0)
21	PB	OS	custom	46.87	46.75	(0)	46.75	(0)
22	LS	OD	custom	41.00	41.00	(0)	41.25	(1)

STATISTICS

The collected data was handled in a statistical manner. First the Kruskal-Wallis One-Way Analysis of Variance (H statistic) was run to determine whether the differences in data among our three independent samples were genuine population differences or whether they merely represented chance variations in the same population.

$$H = \frac{12}{N(N+1)} \sum_{j=1}^{k} \frac{R_j^2}{n_j} - 3(N+1)$$

where k = number of samples
n_j = number of cases in jth sample
$N = \Sigma n_j$, the number of cases in all the samples combined
R_j = sum of ranks in jth sample
$\sum_{j=1}^{k}$ = sum over the k samples

H is distributed approximately as chi square with df=k-1.

Since the Mann-Whitney U statistic is closely related to the H statistic when k=2, individual comparisons between 2 groups by means of the U statistic were made following any significance of an overall H test.[7]

$$U_1 = N_1 N_2 + \frac{N_1(N_1+1)}{2} - \Sigma R_x$$

$$U_2 = N_1 N_2 + \frac{N_2(N_2+1)}{2} - \Sigma R_y$$

where ΣR_x = sum of the ranks for sample x
ΣR_y = sum of the ranks for sample y

It was decided prior to running any data that the 95% confidence level (p=.05) would represent statistical significance in this study.

STATISTICAL SUMMARY TABLES

WEARING TIME

One Week: H statistic value--11.11
H is significant at .01 level

U statistics:

Groups Tested	U value	Significance level
Control vs. Custom	5.0	.01
Control vs. Standard	3.0	.01
Standard vs. Custom	17.5	none

One Month: H statistic value--6.53
H is significant at .05 level

U statistics:

Groups Tested	U value	Significance level
Control vs. Custom	7.5	.05
Control vs. Standard	11.5	.10 only
Standard vs. Custom	21.0	none

COMFORT

One Week: H statistic value--8.52
H is significant at .02 level

U statistics:

Groups Tested	U value	Significance level
Control vs. Custom	5.5	.01
Control vs. Standard	12.5	.10 only
Standard vs. Custom	10.0	.10 only

One Month: H statistic value--16.88
H is significant at .001 level

U statistics:

Groups Tested	U value	Significance level
Control vs. Custom	0.0	.01
Control vs. Standard	1.0	.01
Standard vs. Custom	4.5	.05

PATIENT APPEARANCE

One Week: H statistic value--8.41
H is significant at .02 level

U statistics:

Groups Tested	U value	Significance level
Control vs. Custom	5.5	.01
Control vs. Standard	12.5	.10 only
Standard vs. Custom	12.0	none

One Month: H statistic value--8.66
H is significant at .02 level

U statistics:

Groups Tested	U value	Significance level
Control vs. Custom	5.5	.01
Control vs. Standard	11.5	.10 only
Standard vs. Custom	12.0	none

MOVEMENT & CENTRATION

One Week: H statistic value--15.35
H is significant at .001 level

U statistics:

Groups Tested	U value	Significance level
Control vs. Custom	0.0	.01
Control vs. Standard	3.0	.01
Standard vs. Custom	7.5	.05

One Month: H statistic value--15.97
H is significant at .001 level

U statistics:

Groups Tested	U value	Significance level
Control vs. Custom	0.0	.01
Control vs. Standard	2.0	.01
Standard vs. Custom	6.5	.05

CONJUNCTIVAL INJECTION

One Week: H statistic value--4.43
H is significant at .20 level only

One Month: H statistic value--3.74
H is significant at .20 level only

PERILIMBAL INJECTION

One Week: H statistic value--.87
H is not statistically significant.

One Month: H statistic value--.94
H is not statistically significant.

EDEMA

One Week: H statistic value--.63
H is not statistically significant.

One Month: H statistic value--1.51
H is not statistically significant.

STAINING

One Week: H statistic value--.20
H is not statistically significant.

One Month: H statistic value--.74
H is not statistically significant.

POST-REFRACTION

One Week: H statistic value--.86
H is not statistically significant.

One Month: H statistic value--.74
H is not statistically significant.

VERTICAL POST-KERATOMETER READINGS

One Week: H statistic value--.89
H is not statistically significant.

One Month: H statistic value--.16
H is not statistically significant.

HORIZONTAL POST-KERATOMETER READINGS

One Week: H statistic value--.54
H is not statistically significant.

One Month: H statistic value--.18
H is not statistically significant.

DISCUSSION

The statistical analysis lends itself to the following conclusions. Important differences emerge between the patients whose eyes were fit with the custom modified Polycon lenses and the patients whose eyes were fit with the unmodified Polycons (i.e. control eyes). The custom lenses were significantly more comfortable than the control lenses (p=.01) after one week and one month of wear. It logically follows that the custom lenses could be worn more comfortably for longer periods of time than the control lenses both at one week (p=.01) and at one month (p=.05). If one peruses the data it is readily seen that comfortable wearing time was built up faster (at one week) and then maintained at a higher level (one month) with the custom lenses. Patient appearance was also significantly better with the custom lenses than with the control lenses both at one week and at one month (p=.01). The movement and centration of the lenses, too, were significantly better with the custom than with the control both at one week and at one month (p=.01).

Although the difference is not statistically significant (p=.20 only) the conjunctival injection tended to be less with the custom lenses than with the controls both at one week and at one month. No significant difference exists between the customs

and the controls in the areas of perilimbal injection, staining, edema, post-refraction, and post-keratometer readings.

Differences also exist between the patients whose eyes were fit with the standard modified (blended only) Polycons and patients whose eyes were fit with the unmodified Polycons (controls). The standard modified lenses tended to be more comfortable than the control lenses at one week; however, this relationship fell shy of our set level of statistical significance ($p=.10$ only). At one month of wear, the standard lenses became more comfortable than the controls at a statistically significant level ($p=.01$). The wearing time was significantly longer for the standard lenses than for the control lenses ($p=.01$) at one week; however, at one month wearing times tended to become somewhat more alike. The standard lenses still tended to be comfortably worn for more hours than the control lenses, but the difference was no longer statistically significant ($p=.10$ only). Although the patient appearance tended to be better for those with standard modified lenses than those with the controls both at one week and at one month, the data falls short of statistical significance ($p=.10$ only). The fluorescein pattern (or movement and centration) appeared significantly better with the standard lenses than with the control lenses both at one week and at one month ($p=.01$).

No statistically significant difference was found between the standards and the controls in the areas of injection (conjunctival and perilimbal), staining, edema, post-refraction, and post-k's.

Some differences also exist between the patients who received standard modified lenses and those who received the custom modified lenses. The custom modified lenses tended to be more comfortable

at one week than the standard modified lenses; however, the data fell shy of the set .05 significance level (p=.10 only). At one month, the custom lenses emerged as more comfortable than the standard lenses at a statistically significant level (p=.05).

No statistically significant difference exists between the customs and the standards in the area of wearing time, patient appearance, injection (conjunctival and perilimbal), staining, edema, post-refraction, and post-k's.

Thus, the questions raised at the outset of this study can now be answered. Based on our research, set parameters should not be considered as end points in the fitting of all patients; for, modified lenses perform superiorly in several areas which determine a successful lens fit. As we have seen, lenses modified in a custom (patient-specific) manner lead to better patient appearance and the greatest patient comfort. The patient is able to comfortably build up his wearing time faster than if his lenses were unmodified; and, he is likewise able to comfortably wear his lenses longer each day. Further, conjunctival injection tends to be less for this patient. The fluorescein pattern in a custom lens is superior to both an unmodified and blended-only lens. This may prove to be beneficial after long-term lens wear; however, work needs to be done in the area of long-term wear with modified and unmodified Polycon lenses. The necessarily short follow-up period (one month) in our study was not long enough for the physiological parameters we were following to exhibit anything of statistical significance. A much better indication of the effects on these parameters would be seen after six months to one year of wear.

For the practitioner most interested in fitting Polycon lenses successfully it has been shown that it would be quite worthwhile to modify the lenses in a patient-specific manner. It is interesting to note that the data indicates if the practitioner does not go as far as to fully custom-modify the lenses, even a thorough blending of the peripheries will yield some improvement over unmodified lenses in the areas of patient comfort, patient appearance, wearing times, and fluorescein patterns.

Also of great import would be the availability from Syntex of a wider variety of diameters and other parameters. This would alleviate the need to undertake some of the more major modifications (e.g. size reduction) which may discourage the practitioner concerned with rapidity of service.

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